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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,420	02/13/2001	Gary A. Shangold	ORT-1373	1909

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EXAMINER	
TRAVERS, RUSSELL S	

ART UNIT	PAPER NUMBER
1617	15

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/782,420	Shangold et al
Examiner	**Art Unit**
R.S. Travers J.D., Ph.D.	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 4, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *18-22* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *18-22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The response filed August 4, 2003 has been received and entered into the file.

Applicant's arguments filed August 4, 2003 have been fully considered but they are not deemed to be persuasive in view of the newly presented rejection.

Claims 18-22 are presented for examination.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 18-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Bergink (415) in view of Darney et al and Alapiessa et al, of record, or newly cited.

Bergink (415) teaches the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for contraception employing triphasic dosage forms. Bergink teaches triphasic combined oral contraceptive methods, compositions

and kits substantially similar to those herein claimed, as old and well known in the art (see abstract, claims, and pages 4-9). Claims 18-22 and the primary reference, differ as to:

1) administration levels of the medicaments, and

2) the employment of these medicaments in a 21 day regimen

Determining the active ingredient dosage level required to effect optimal contraceptive benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. In the instant case Darney et al teach, based on a published report (Johns Hopkins School of Public Health: IUDs- An update *Population Reports* 1995. XXII(5). Series B) oral contraceptives containing ethinyl estradiol at levels greater than 20 micrograms provided a lower incidence of breakthrough bleeding and spotting as compared to higher levels of ethinyl estradiol (Darney et al, page 2, paragraph bridging columns 2 and 3). The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed contraceptive methods, and compositions.

Bergink teaches employment of a contraceptive regimen in a triphasic 24 day cycle. Alapiessa et al teach the employment of ethinyl estradiol at levels greater than

20 micrograms in combination with desogestrel at levels herein recited administered in a 21 day regimen. The skilled artisan would be motivated to employ this 21 day regimen by Bergink (page 2, line 4) teaching the persistent attempts by those in the field of contraception to "lower the total steroid dosage" in any contraceptive regimen.

Thus, in the instant case, numerous motivations exist to modify the Examiner cited prior art into the presented invention. Possessing these teachings, the skilled artisan would have been motivated to employ ethinyl estradiol at levels greater than 20 micrograms provided a lower incidence of breakthrough bleeding and spotting thereby rendering the presented claims obvious.

RESPONSE TO ARGUMENTS

Those arguments presented have been considered but are unconvincing. Examiner notes the instant compounds are old and well known for providing contraceptive benefits; with the physiological activity for each compound well known to the skilled artisan. Examiner cited prior art teaches numerous 21 day hormone administration regimens, albeit none anticipating those herein recited (see Bergink, page 2 (entire page)). Variance of the hormone dosage, and adjustment of the administration period are recited in the Examiner cited prior art, yet the instant specific regimen is not illustrated. Lack of anticipation fails to erode the obvious nature of the subject matter recited in the instant claims. That regimen herein claimed is averred as

providing some unexpected benefits flowing from the optimization of the dosage levels, and timing of the medicament administration. As stated earlier, motivation to employ the hormone levels herein claimed reside in the cited prior art, with the 21 day administration regimen supplied by the examienr cited prior art. To employ the specific dosages herein claimed would be seen as optimization of a conventional contraceptive method.

Applicants aver unexpected benefits residing in the claimed subject matter, yet fail to fails to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is neither clear and convincing, nor reasonably commensurate in scope with the instant claims. Absent claims commensurate with a clear and convincing showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

It is well known by the skilled artisan that carriers and excipients are employed to enhance the activity of active ingredients. Thus, the skilled artisan would expect conventional excipients and carriers to be useful concomitantly, absent information to the contrary. The instant carriers and excipients are not employed concomitantly in the prior art, thus only obviate their concomitant use.

Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

Examiner would favorably consider claims directed to those medicaments providing unexpected therapeutic benefits, as averred herein.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY

PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617